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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,534	04/15/2004	G. Ian Rowlandson	IT140825 (5024-00118)	8247

26753 7590 07/05/2006

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EXAMINER

HELLER, TAMMIE K

ART UNIT PAPER NUMBER

3766

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/825,534	<b>Applicant(s)</b> ROWLANDSON, G. IAN	
	<b>Examiner</b> Tammie Heller	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/9/06, 3/22/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. In view of Applicant's arguments, the Examiner is withdrawing the rejection of claims 1-20 under 35 U.S.C. 112, first paragraph, which was made against claims 1-20 in the previous Office Action.

### ***Response to Arguments***

2. Applicant's arguments, see pages 3-7, filed March 9, 2006, with respect to the rejection(s) of claim(s) 1-20 under 35 U.S.C. 102 and 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of previously uncited prior art.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, and 5-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Lozier et al. (US 2004/0230456), herein Lozier. Regarding claims 1 and 11, Lozier discloses a system for identifying patients who may be at risk for sudden cardiac death. The method of Lozier includes the steps of acquiring patient data from a plurality of

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medical equipment databases (see paragraph 5, ln. 5-10) and analyzing the patient data to determine a sudden cardiac death risk score (see paragraph 13, ln. 10-14).

5. Regarding claim 2, Lozier discloses that multiple independent indications of sudden cardiac death are generated based on the patient data acquired from the plurality of medical equipment databases (see paragraph 4, ln. 12-18 and paragraph 13, ln. 14-17).

6. Regarding claim 5, Lozier discloses that the patient data includes electrocardiogram data (see paragraph 5), and the electrogram data may be compared to stored electrogram patterns to determine an electrogram measurement (see paragraph 11).

7. Regarding claim 6, the program described by Lozier is inherently capable of producing a correlation measurement between the electrogram of the patient and a range of electrogram values from the general population.

8. Regarding claim 7, Lozier discloses determining a mathematical measurement based on the value of a given parameter (see paragraph 3, ln. 12-15).

9. Regarding claim 8, the program of Lozier is inherently capable of producing a correlation measurement between the mathematical measurement of the patient and a range of values from the general population.

10. Regarding claim 9, Lozier discloses that the diagnosis of sudden death is based on the electrogram reading and mathematical correlation (see paragraph 9).

11. Regarding claim 10, Lozier includes the electrogram data and sudden cardiac death risk score in a single report (see paragraph 19).

12. Regarding claim 12, the invention of Lozier is directed towards a computer program which acquires patient data from medical equipment databases, analyzes the patient data to calculate a plurality of measurements, diagnoses the patient based on the plurality of measurements, and reports to the user a sudden cardiac death score (see paragraphs 11 and 16).

13. Regarding claim 13, the Lozier reports to the user a physician identifier 208, a patient identifier 201, a diagnosis 205, and other various values for the patient (see Figure 2).

14. Regarding claims 14-16, Lozier discloses a variety of patient parameter measurements in Figure 2. The Examiner takes the position that it is inherent within the method and program of Lozier that the analysis module accesses the electrocardiogram data in order to produce the likeliness indication at 202, includes a mathematical relationship module in order to produce the EF% value at 203, and a decision support module in order to produce the indications at 204, 205, and 206.

15. Regarding claim 17, the invention of Lozier is directed towards a computer program which reports to the user data acquired from a plurality of medical devices which includes a physician identifier 208, a patient identifier 201, an electrogram measurement 203, and a diagnosis 205 (see Figure 2).

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 3, 4, and 18-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Lozier in view of Guerrero, cited in previous Office Action. Lozier discloses the invention essentially as claimed, but fails to disclose the use of patient image data to produce the sudden cardiac death score. Guerrero discloses a method of analyzing biological signals via a computerized visual analysis technique, CVAT. Guerrero further discloses that CVAT, in conjunction with Holter monitoring, is an effective method of detecting an increased risk of arrhythmia and sudden cardiac death (see col. 24, ln. 54-56). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize the CVAT method of Guerrero in conjunction with the invention of Lozier in order to provide a method of detecting sudden cardiac death, and thus provide a more accurate sudden cardiac death risk score.

### ***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Xue et al. (U.S. 2005/0004481) which discloses a system and method for diagnosing based on ECG measurements;

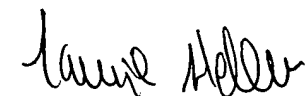
Mischynski et al. (U.S. 2002/0188214) which discloses a device and process for analyzing a medical condition of a user.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-

1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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